

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Engelhardt et al

Serial No. 08/479,997

Filed: June 7, 1995

Title: OLIGO- AND POLYNUCLEOTIDES  
 COMPRISING PHOSPHATE MOIETY  
 LABELED NUCLEOTIDES

Group Art Unit: 1631

Examiner: Ardin H. Marschel, Ph.D.

527 Madison Avenue, 9<sup>th</sup> Floor  
 New York, New York 10022  
 April 29, 2004

**FILED VIA EXPRESS MAIL**

Mail Stop Missing Parts  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§1.56 & 1.97-1.98**

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following thirty-eight (38) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

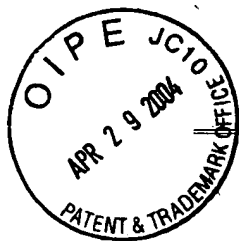
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Engelhardt, et al

Serial No.: 08/479,997

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Page 2 [Supplemental Information Disclosure Statement – April 29, 2004]

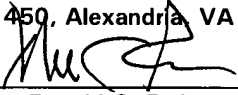


**EXPRESS MAIL CERTIFICATE**

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Deposit Date: April 29, 2004

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Ronald C. Fedus  
Reg. No. 32,567

APRIL 29 2004  
Date

1. Adams, P.L., et al., Davidson's The Biochemistry of the Nucleic Acids, 8<sup>th</sup> Edition, Academic Press, New York, pp. 298-299 (1976) [Exhibit 1];
2. Anderson, K.P., et al., U.S. Patent No. 5,591,720, filed August 14, 1991 [Exhibit 2];
3. Baker, B.E., U.S. Patent No. 5,643,780, filed October 21, 1994 [Exhibit 3];
4. Banker, M.J., et al., U.S. Patent No. 5,643,730, filed March 14, 1995 [Exhibit 4];
5. Birch, G.G., et al., "Structural Functions and Taste in the Sugar Series; The Structural Basis of Bitterness in Sugar Analogues," J. of Food Science 41:1403-1407 (1976) [Exhibit 5];
6. Chladek, S., et al., "Synthesis and Properties of Nucleoside 5'-Phosphoazidates Derived from Guanosine and Adenosine Nucleotides: Effect on Elongation Factors G and Tu Dependent Reactions," Biochemistry 16:4312-4319 (1977) [Exhibit 6];
7. Cook, P.D., et al., U.S. Patent No. 5,614,617, filed July 1, 1991 [Exhibit 7];
8. Crooke, S.T., et al., U.S. Patent No. 5,811,232, filed August 5, 1996 [Exhibit 8];
9. Darlix, J.L., et al., "Analysis of Transcription *in Vitro* Using Purine Nucleotide Analogs," Biochemistry 10:1525-1531 (1971) [Exhibit 9];
10. Darlix, J.L., et al., "Restriction of gene transcription by nucleotide analogs," Biochimie 56:703-710 (1974) [Exhibit 10];
11. Ecker, D.J., et al., U.S. Patent No. 5,874,564, filed June 5, 1995 [Exhibit 11];
12. Ecker, D.J., et al., U.S. Patent No. 5,736,924, filed June 27, 1991 [Exhibit 12];
13. Ecker, D.J., U.S. Patent No. 5,591,600, filed March 18, 1992 [Exhibit 13];
14. Eigen, M., et al., U.S. Patent No. 5,807,677, filed December 19, 1995 [Exhibit 14];

15. Geider, K., "DNA Synthesis in Nucleotide-Permeable *Escherichia coli* Cells," Eur. J. Biochem. 27:554-563 (1972) [Exhibit 15];
16. Keppler, D.O.R., et al., "Uridylate trapping, induction of UTP deficiency, and stimulation of pyrimidine synthesis *de novo* by D-galactosone," Biochem J. 206:139-146 (1982) [Exhibit 16];
17. Kornberg, A., DNA Replication, W.H. Freeman & Company, San Francisco, Chapter 12, pp. 415-441, "Inhibitors of Replication" (1980) [Exhibit 17];
18. Kornberg, A., DNA Synthesis, W.H. Freeman & Company, San Francisco, Chapter 7, pp. 227-228, "Replication" (1974) [Exhibit 18];
19. Korytnyk, W., et al., "CMP and CMP-sugar analogs as inhibitors of sialic acid incorporation into glycoconjugates," Eur. J. Med. Chem. – Chimica Therapeutica 15:77-84 (1980) [Exhibit 19];
20. Langen, P., Antimetabolites of Nucleic Acid Metabolism, Gordon and Breach, New York, translated from German by Dr. Thomas A. Scott, pp. 143-187 (1975) [Exhibit 20];
21. Lartey, P.A., et al., "Preparation and Study of a Fluorescent Sugar Analog Competitive Inhibitor of Yeast Hexokinase," Preparative Biochemistry 9:85-95 (1979) [Exhibit 21];
22. Liu, et al., U.S. Patent No. 5,914,230, filed December 20, 1996 [Exhibit 22];
23. Marcus, F., "Inhibition of Fructose 1,6-Bisphosphatase by 9-B-D-Arabinofuranosyladenine 5'-Monophosphate," Cancer Research 36:1847 (1976) [Exhibit 23];
24. Martin, F.J., et al., U.S. Patent No. 5,891,468, filed October 10, 1997 [Exhibit 24];
25. Pagano, J.S., et al., U.S. Patent 5,242,906, filed April 22, 1991 [Exhibit 25];
26. Piperno, J.R., et al., "An ATP Stimulation of T4 DNA Polymerase Mediated via T4 Gene 44/62 and 45 Proteins," Journal of Biological Chemistry 253:5174-5179 (1978) [Exhibit 26];

27. Rahman, A., et al., U.S. Patent No. 5,665,710, filed December 10, 1993 [Exhibit 27];
28. Reha-Krantz, L.J., et al., "Bacteriophage T4 DNA Polymerase Mutations That Confer Sensitivity to the PPI Analog Phosphonoacetic Acid," J. of Virology 67:60-66 (1993) [Exhibit 28];
29. Roberts, K.R., et al., "Effects of 2-deoxy D-glucose and other sugar analogues on acid production from sugars by human dental plaque bacteria," Scandinavian Journal of Dental Research 88:201-209 (1980) [Exhibit 29];
30. Ryser, H.J.P., et al., U.S. Patent No. 4,847,240, filed October 7, 1987 [Exhibit 30];
31. Scheit, K.H., Nucleotide Analogs: Synthesis and Biological Function, John Wiley & Sons, New York, 280 pages (1980) [Exhibit 31];
32. Schwartz, D.E., et al., U.S. Patent No. 5,212,059, filed January 9, 1989 [Exhibit 32];
33. Simoncsits, A., et al., "A New Type of Nucleoside 5'-Triphosphate Analogue: P1-(Nucleoside 5"-) P1-Amino-Triphosphates," Tetrahedron Letters 44:3995-3998 (1976) [Exhibit 33];
34. Stoeckler, J.D., et al., "Human Erythrocytic Purine Nucleoside Phosphorylase: Reaction with Sugar-Modified Nucleoside Substrates," Biochemistry 19:102-107 (1980) [Exhibit 34];
35. Stridh, S., et al., "The Effect of Pyrophosphate Analogues on Influenza Virus RNA Polymerase and Influenza Virus Multiplication," Archives of Virology 61:245-250 (1979) [Exhibit 35];
36. Usman, N., et al., U.S. Patent No. 5,652,094, filed January 31, 1992 [Exhibit 36];
37. Wright, J.A., et al., U.S. Patent No. 5,998,383, filed August 1, 1997 [Exhibit 37];
38. Yang, B.I-Y, et al., "Pyridoxal 5'-Phosphate and Analogs as Probes of Coenzyme-Protein Interaction," Methods of Enzymology 62:528-551 (1979) [Exhibit 38].

The thirty-eight (38) foregoing references (numbers 1-38) have come to the attention of the Applicants' Attorney.

A completed Form PTO-1449 listing the 38 above-submitted documents is also attached hereto as Exhibit 39.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

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Serial No.: 08/479,997

Filed: June 7, 1995

Page 7 [Supplemental Information Disclosure Statement – April 29, 2004]

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



Ronald C. Fedus

Registration No. 32,567

Natalie Bogdanos

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Attorneys for Applicants

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Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

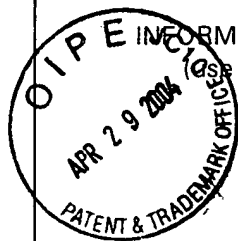
Atty. Docket No.  
ENZ-5(D6)(C2)

Serial No. 08/479,997

Applicants: Engelhardt, et al

Filed: June 7, 1995

Group: 1631


 INFORMATION DISCLOSURE CITATION  
 (Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT NUMBER | DATE     | NAME            | CLASS | SUB<br>CLASS | FILING<br>DATE IF<br>APPRO-<br>PRIATE |
|---------------------|-----------------|----------|-----------------|-------|--------------|---------------------------------------|
|                     | 5 5 9 1 7 2 0   | 8/14/91  | Anderson, et al |       |              |                                       |
|                     | 5 6 4 3 7 8 0   | 10/21/94 | Baker, B.E.     |       |              |                                       |
|                     | 5 6 4 3 7 3 0   | 3/14/95  | Banker, et al   |       |              |                                       |
|                     | 5 6 1 4 6 1 7   | 7/1/91   | Cook, et al     |       |              |                                       |
|                     | 5 8 1 1 2 3 2   | 8/5/96   | Crooke, et al   |       |              |                                       |
|                     | 5 8 7 4 5 6 4   | 6/5/95   | Ecker, et al    |       |              |                                       |
|                     | 5 7 3 6 9 2 4   | 6/27/91  | Ecker, et al    |       |              |                                       |
|                     | 5 5 9 1 6 0 0   | 3/18/92  | Ecker, et al    |       |              |                                       |

## FOREIGN PATENT DOCUMENTS

| DOCUMENT NUMBER | DATE | NAME | CLASS | SUB<br>CLASS | TRAN-<br>SLATION<br>YES NO |
|-----------------|------|------|-------|--------------|----------------------------|
|                 |      |      |       |              |                            |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |   |
|--|---|
|  | Adams, P.L., et al., <u>Davidson's The Biochemistry of the Nucleic Acids</u> , 8 <sup>th</sup> Edition, Academic Press, New York, pp. 298-299 (1976)  |
|  | Birch, G.G., et al., "Structural Functions and Taste in the Sugar Series; The Structural Basis of Bitterness in Sugar Analogues," <u>J. of Food Science</u> 41:1403-1407 (1976)   |
|  | Chladek, S., et al., "Synthesis and Properties of Nucleoside 5'-Phosphoazidates Derived from Guanosine and Adenosine Nucleotides: Effect on Elongation Factors G and Tu Dependent Reactions," <u>Biochemistry</u> 16:4312-4319 (1977) |
|  | Darlix, J.L., et al., "Analysis of Transcription <i>in Vitro</i> Using Purine Nucleotide Analogs," <u>Biochemistry</u> 10:1525-1531 (1971)  |
|  | Darlix, J.L., et al., "Restriction of gene transcription by nucleotide analogs," <u>Biochimie</u> 56:703-710 (1974)   |
|  | Geider, K., "DNA Synthesis in Nucleotide-Permeable <i>Escherichia coli</i> Cells," <u>Eur. J. Biochem.</u> 27:554-563 (1972)  |

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

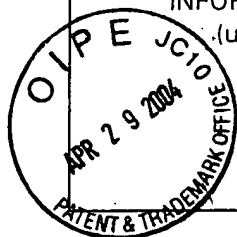


Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

## INFORMATION DISCLOSURE CITATION

(use several sheets if necessary)

Atty. Docket No.  
ENZ-5(D6)(C2)

Serial No. 08/479,997

Applicants: Engelhardt, et al

Filed: June 7, 1995

Group: 1631

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|---------------------|-----------------|----------|---------------|-------|--------------|---------------------------------------|
|                     | 5 8 0 7 6 7 7   | 12/19/95 | Eigen, et al  |       |              |                                       |
|                     | 5 9 1 4 2 3 0   | 12/20/96 | Liu, et al    |       |              |                                       |
|                     | 5 8 9 1 4 6 8   | 10/10/97 | Martin, et al |       |              |                                       |
|                     | 5 2 4 2 9 0 6   | 4/22/91  | Pagano, et al |       |              |                                       |
|                     | 5 6 6 5 7 1 0   | 12/10/93 | Rahman, et al |       |              |                                       |

## FOREIGN PATENT DOCUMENTS

| DOCUMENT NUMBER | DATE | NAME | CLASS | SUB<br>CLASS | TRAN-<br>SLATION<br>YES NO |
|-----------------|------|------|-------|--------------|----------------------------|
|                 |      |      |       |              |                            |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |  |
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|  | Keppler, D.O.R., et al., "Uridylate trapping, induction of UTP deficiency, and stimulation of pyrimidine synthesis <i>de novo</i> by D-galactosone," Biochem J. 206:139-146 (1982) |
|  | Kornberg, A., <u>DNA Replication</u> , W.H. Freeman & Company, San Francisco, Chapter 12, pp. 415-441, "Inhibitors of Replication" (1980)  |
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|  | Marcus, F., "Inhibition of Fructose 1,6-Bisphosphatase by 9-B-D-Arabinofuranosyladenine 5'-Monophosphate," Cancer Research 36:1847 (1976)  |
|  | Piperno, J.R., et al., "An ATP Stimulation of T4 DNA Polymerase Mediated via T4 Gene 44/62 and 45 Proteins," Journal of Biological Chemistry 253:5174-5179 (1978)                  |
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Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

Atty. Docket No.  
ENZ-5(D6)(C2)

Serial No. 08/479,997

INFORMATION DISCLOSURE CITATION  
(Use several sheets if necessary)

Applicants: Engelhardt, et al

Filed: June 7, 1995

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|---------------------|-----------------|---------|-----------------|-------|--------------|---------------------------------------|
|                     | 4 8 4 7 2 4 0   | 10/7/87 | Ryser, et al    |       |              |                                       |
|                     | 5 2 1 2 0 5 9   | 1/9/89  | Schwartz, et al |       |              |                                       |
|                     | 5 6 5 2 0 9 4   | 1/31/92 | Usman, et al    |       |              |                                       |
|                     | 5 9 9 8 3 8 3   | 8/1/97  | Wright, et al   |       |              |                                       |
|                     |                 |         |                 |       |              |                                       |

## FOREIGN PATENT DOCUMENTS

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|-----------------|------|------|-------|--------------|----------------------------|
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|                 |      |      |       |              |                            |

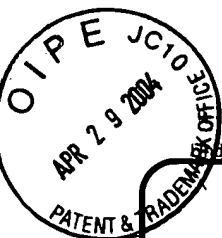
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|--|--|
|  | Roberts, K.R., et al., "Effects of 2-deoxy D-glucose and other sugar analogues on acid production from sugars by human dental plaque bacteria," <u>Scandinavian Journal of Dental Research</u> 88:201-209 (1980) |
|  | Scheit, K.H., <u>Nucleotide Analogs: Synthesis and Biological Function</u> , John Wiley & Sons, New York, 280 pages (1980)   |
|  | Simoncsits, A., et al., "A New Type of Nucleoside 5'-Triphosphate Analogue: P1-(Nucleoside 5'-) P1-Amino-Triphosphates," <u>Tetrahedron Letters</u> 44:3995-3998 (1976)  |
|  | Stoeckler, J.D., et al., "Human Erythrocytic Purine Nucleoside Phosphorylase: Reaction with Sugar-Modified Nucleoside Substrates," <u>Biochemistry</u> 19:102-107 (1980)   |
|  | Stridh, S., et al., "The Effect of Pyrophosphate Analogues on Influenza Virus RNA Polymerase and Influenza Virus Multiplication," <u>Archives of Virology</u> 61:245-250 (1979)                                  |
|  | Yang, B.I-Y, et al., "Pyridoxal 5'-Phosphate and Analogs as Probes of Coenzyme-Protein Interaction," <u>Methods of Enzymology</u> 62:528-551 (1979)  |
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EXAMINER

DATE CONSIDERED

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*Ign*

*04-30-04*

*1631*

PTO/SB/17 (10-03)

Approved for use through 07/31/2006. OMB 0651-0032  
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# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ ) 180.00

## Complete if Known

|                      |                          |
|----------------------|--------------------------|
| Application Number   | 08/479,997               |
| Filing Date          | June 7, 1995             |
| First Named Inventor | Engelhardt               |
| Examiner Name        | Ardin H. Marschel, Ph.D. |
| Art Unit             | 1631                     |
| Attorney Docket No.  | Enz-5(D6)(C2)            |

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit  
Account  
Number  
Deposit  
Account  
Name

05-1135

Enzo Biochem

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity<br>Fee Code (\$) | Small Entity<br>Fee Code (\$) | Fee Description        | Fee Paid |
|-------------------------------|-------------------------------|------------------------|----------|
| 1001 770                      | 2001 385                      | Utility filing fee     |          |
| 1002 340                      | 2002 170                      | Design filing fee      |          |
| 1003 530                      | 2003 265                      | Plant filing fee       |          |
| 1004 770                      | 2004 385                      | Reissue filing fee     |          |
| 1005 160                      | 2005 80                       | Provisional filing fee |          |

SUBTOTAL (1) (\$ ) 0

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

|                    | Extra Claims | Fee from below | Fee Paid |
|--------------------|--------------|----------------|----------|
| Total Claims       | -20** =      | X              |          |
| Independent Claims | -3** =       | X              |          |
| Multiple Dependent |              |                |          |

| Large Entity<br>Fee Code (\$) | Small Entity<br>Fee Code (\$) | Fee Description  |
|-------------------------------|-------------------------------|--|
| 1202 18                       | 2202 9                        | Claims in excess of 20                                     |
| 1201 86                       | 2201 43                       | Independent claims in excess of 3                          |
| 1203 290                      | 2203 145                      | Multiple dependent claim, if not paid                      |
| 1204 86                       | 2204 43                       | ** Reissue independent claims over original patent         |
| 1205 18                       | 2205 9                        | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) (\$ ) 0

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity Small Entity

| Fee Code (\$) | Fee Code (\$) | Fee Description  | Fee Paid |
|---------------|---------------|--|----------|
| 1051 130      | 2051 65       | Surcharge - late filing fee or oath  |          |
| 1052 50       | 2052 25       | Surcharge - late provisional filing fee or cover sheet                     |          |
| 1053 130      | 1053 130      | Non-English specification  |          |
| 1812 2,520    | 1812 2,520    | For filing a request for ex parte reexamination                            |          |
| 1804 920*     | 1804 920*     | Requesting publication of SIR prior to Examiner action                     |          |
| 1805 1,840*   | 1805 1,840*   | Requesting publication of SIR after Examiner action                        |          |
| 1251 110      | 2251 55       | Extension for reply within first month                                     |          |
| 1252 420      | 2252 210      | Extension for reply within second month                                    |          |
| 1253 950      | 2253 475      | Extension for reply within third month                                     |          |
| 1254 1,480    | 2254 740      | Extension for reply within fourth month                                    |          |
| 1255 2,010    | 2255 1,005    | Extension for reply within fifth month                                     |          |
| 1401 330      | 2401 165      | Notice of Appeal   |          |
| 1402 330      | 2402 165      | Filing a brief in support of an appeal                                     |          |
| 1403 290      | 2403 145      | Request for oral hearing   |          |
| 1451 1,510    | 1451 1,510    | Petition to institute a public use proceeding                              |          |
| 1452 110      | 2452 55       | Petition to revive - unavoidable   |          |
| 1453 1,330    | 2453 665      | Petition to revive - unintentional   |          |
| 1501 1,330    | 2501 665      | Utility issue fee (or reissue)   |          |
| 1502 480      | 2502 240      | Design issue fee   |          |
| 1503 640      | 2503 320      | Plant issue fee  |          |
| 1460 130      | 1460 130      | Petitions to the Commissioner  |          |
| 1807 50       | 1807 50       | Processing fee under 37 CFR 1.17(q)  |          |
| 1806 180      | 1806 180      | Submission of Information Disclosure Stmt                                  | 180.00   |
| 8021 40       | 8021 40       | Recording each patent assignment per property (times number of properties) |          |
| 1809 770      | 2809 385      | Filing a submission after final rejection (37 CFR 1.129(a))                |          |
| 1810 770      | 2810 385      | For each additional invention to be examined (37 CFR 1.129(b))             |          |
| 1801 770      | 2801 385      | Request for Continued Examination (RCE)                                    |          |
| 1802 900      | 1802 900      | Request for expedited examination of a design application                  |          |

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ ) 180.00

## SUBMITTED BY

(Complete if applicable)

|                   |                    |                                   |                |           |              |
|-------------------|--------------------|-----------------------------------|----------------|-----------|--------------|
| Name (Print/Type) | Ronald C. Fedus    | Registration No. (Attorney/Agent) | 32,567         | Telephone | 212-583-0100 |
| Signature         | <i>[Signature]</i> | Date                              | April 29, 2004 |           |              |

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